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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,299	03/12/2004	Gerald Horn	114309-1017	7833

7590 03/19/2009

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EXAMINER	
HAND, MELANIE JO	
ART UNIT	PAPER NUMBER
3761	
MAIL DATE	DELIVERY MODE
03/19/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/799,299	HORN, GERALD	
	Examiner	Art Unit	
	MELANIE J. HAND	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/9/09,3/11/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 9, 2009 has been entered.

Information Disclosure Statements

2. The information disclosure statements (IDS) submitted on January 9, 2009 and March 11, 2009 were filed after the mailing date of the final action on July 9, 2008. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Response to Arguments

3. Applicant's arguments filed January 9, 2009 have been fully considered but they are not persuasive. With respect to arguments regarding claim 33: Applicant argues that the combination of references relied upon to reject claim 33 is based upon improper hindsight. Examiner had previously stated that the motivation to combine can be found in the secondary references, which applicant disagrees with because the secondary references are different applications. The common thread between these three secondary references, as applicant correctly notes, is the use of phentolamine. Phentolamine is an alpha receptor antagonist that is a known agent in the art for treating sexual dysfunction as supported by these secondary

references. Therefore, since these references disclose phentolamine, a composition identical to that disclosed and claimed for the pharmaceutically active compound, the benefit (i.e. the motivation) of using phentolamine will be identical tot he benefit disclosed by applicant. The fact that the secondary references are all directed to compounds for treating sexual dysfunction is immaterial, as this is merely one intended use of phentolamine and in fact, as stated in the previous action, applicant explicitly discloses that the imidazolines, specifcially phentolamine, that are known in the art and used to treat sexual dysfunction can be used in the recited specifically active composition. This amounts to an admission by applicant that, not only is the use of phentolamine known in the art, its use in the art of treatments for sexual dysfunction is equally well known. Examiner has altered the rejection to rely on only the Gerstenberg reference as a secondary reference to make it clear that modifying the formulation of Gluchowski by using phentolamine as the imidazoline as disclosed by Gerstenberg meets the limitation of a pharmaceutically active compound consisting essentially of phentolamine in a therapeutically effective amount as that term is understood from the disclosure. The benefits claimed of pupil contraction, reduction and reduction of redness are inherent in such a compound because it is identical to that claimed and Gerstenberg discloses that the phentolamine is used in a manner (treatment of sexual dysfunction) that makes it also acceptable for use in the human eye, as stated by applicant. Thus the functional limitations as to pupil contraction and redness are obvious over the combined teaching of Gluchowsi in view of Gerstenberg.

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gluchowski (U.S. Patent No. 5,252,295) in view of Gerstenberg et al (U.S. Patent No. 5,236,904).

With respect to **claim 33:** Gluchowski teaches an ophthalmic formulation, comprising: a sterile aqueous carrier in the form of saline; and a pharmaceutically active compound consisting essentially of an imidazoline in a therapeutically effective amount. (Col. 4, lines 5-8, 15-20) The limitation "to contract a pupil of a human patient's eye in dim light so that the pupil is effectively reduced to improve vision in dim light and further to minimize eye redness" constitutes functional language that is given little patentable weight herein.

Gluchowski does not teach a pharmaceutically active compound consisting essentially of phentolamine. Applicant states in the Specification that alpha 1 antagonists such as phentolamine that are used to treat sexual dysfunction (interpreted herein as "those known in the art for treating sexual dysfunction") can be used as the claimed pharmaceutically active compound of the claimed invention. (Specification, Page 3, line 29 – Page 4, line 4) This constitutes an admission by applicant that not only is the use of phentolamine known, its use in the art of treatments of sexual dysfunction is also known. Gerstenberg discloses such use of phentolamine in a sexual dysfunction treatment compound, and therefore according to applicant's admission, if used as the imidazoline in the compound of Gluchowski, will yield a formulation identical to that disclosed by applicant and therefore inherently provide the benefits

of pupil contraction/reduction to improve vision in dim light and further reduce redness. Thus although neither Gluchowski nor Gerstenberg explicitly meets the functional limitations pertaining to pupil contraction, reduction to improve vision or redness, it would be obvious to one of ordinary skill in the art to modify the formulation of Gluchowski such that the imidazoline is phentolamine with a reasonable expectation of success, as phentolamine as an alpha 1 receptor antagonist controls the degree of iris dilation (or contraction in environments with less light), which results in control of pupil contraction.

With respect to **claim 34:** Gluchowski teaches that the active agent is present in an amount between 0.0001-1% weight by volume solvent (g/cc). Gluchowski teaches a composition having 300 ml water, therefore the active agent is present in an amount between 30-3,000 mg/cc, which overlaps the range set forth in claim 34. (Col. 4, lines 20-25, Col. 12, lines 48-50)

With respect to **claim 35:** The sterile aqueous carrier taught by Gluchowski comprises saline, which is an ophthalmic artificial tear solution. (Col. 4, lines 5-7)

With respect to **claim 36:** The formulation fairly suggested by Gluchowski meets all of the remaining claim limitations of claim 36. With respect to the limitation "the pupil is effectively reduced by 1.0 mm or more", this limitation is rendered obvious by Gluchowski because the formulation consisting essentially of phentolamine that is fairly suggested by Gluchowksi will necessarily meet this limitation by virtue of meeting all of the other claim limitations as to the claimed formulation. The motivation to modify the formulation so as to consist essentially of phentolamine is stated *supra* with respect to claim 33.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE J. HAND whose telephone number is (571)272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie J Hand/
Examiner, Art Unit 3761